Veterinary Medicines Directorate

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Post Authorisation Assessments

Flypor 4% w/v Pour-on Solution

Vm 52127/5067

12 March 2025	Change of Marketing Authorisation Holder from: Elanco Europe Ltd., Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom to: Elanco GmbH, Heinz-Lohmann Strasse 4, Groden, D-27472 Cuxhaven, Germany.
19 January 2025	Addition of pack size.
09 September 2020	Change in the address of the Marketing Authorisation Holder from Elanco Europe Ltd, Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom to Elanco Europe Ltd, Form 2, Bartley Way, Bartley Wood Business Park, Hook, RG27 9XA, United Kingdom.
05 June 2019	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
06 July 2017	Change in the name and address of a manufacturer of the finished product, also responsible for batch release.
07 March 2017	Introduction of a new pharmacovigilance system.
19 January 2017	Increase in batch size of the finished product. Minor change in the manufacturing process.
15 December 2015	Change of MAH holder and Distributor from Novartis Animal Health UK Ltd to Elanco Europe Ltd.
28 November 2012	Updates to sections 4.2 and 5.1 of the SPC regarding in vitro efficacy against Culicoides.
23 August 2012	Deletion of manufacturing site of an active substance
09 February 2010	Approval of previously unseen mock ups
12 August 2009	Minor change in the manufacture of the finished product
24 March 2009	Addition of a manufacturer of the active substance
05 June 2008	Change of legal category from PML to POM-VPS Changes to the SPC and Product Literature to bring in line with new legislation
21 August 2007	Change of address of the MAH and Distributor
27 November 2006	Renewal
31 January 2001	Change of MAH
25 September 2000	Renewal
31 March 2000	QC procedures
09 September 1999	Change to manufacturing site of the dosage form Change of manufacturer of the dosage form